TeleHealthCare America, LLC 8700 W. Flagler Street #200 Miami, FL 33174

Response to FCC in the Matter of Promoting Telehealth for Low-Income Consumers NOTICE OF INQUIRY Promoting Telehealth for Low-Income Consumers WC Docket. No. 18-213

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1. INTRODUCTION

TeleMedCare America (**TMC**) is a Florida Limited Liability Corporation filed on April 29, 2016, in business with the NEAT Group conglomerate (<u>www.neat-group.com</u>), subsidiary of Le Grand, S.A. and Telemedcare Pty Ltd of Australia. The NEAT Group and its products are present in Argentina, Central America, Germany, Spain, Sweden, the United States, and Switzerland. In Florida, TMC is a start-up business based on a relatively new technology. In the Unites States TMC offers telehealth services of the type known as Remote Patient Monitoring (RPM).

Should an RFP develop from this **request for information (RFI)**, TMC intends to submit a proposal for FCC's consideration in partnership with the Westchester General Hospital located at 2500 SW 75th Avenue, Miami, FL 33155. This hospital accepts Medicaid and serves a primarily low-income Hispanic population and veterans (accepts TriCare). In addition, TMC shall partner with TracFone, our current 4G (LTE) broadband provider.

TMC is predominantly focused on providing RPM services proven to reduce the incidence of rehospitalization, emergency room visits, hospital length of stay (LOS), morbidity, and mortality by monitoring health indicators of patients afflicted with certain chronic diseases. The RPM system and procedures allows for more frequent assessment of patients' medical conditions from patients' residences by medical specialists at distant sites. It guarantees adherence and more frequent Continuity of Care (COC) hence improving the management of chronic diseases.

17-27 Goals of the Proposed Pilot Program

TMC concurs with points 17 through 27 of the RFI in that greater accessibility to broadband will increase the use of RPM by a rapidly growing elderly population afflicted with various chronic diseases that accounts for increased cost to Medicaid. Countless medical trials in the US and EU suggest the use of RPM will mitigate the rising cost and improve the medical treatment of the target population.

TMC is cognizant that Florida is especially impacted by a senior population that is growing faster than the national rate. Persons aged 65 years and older comprised 12.4% of the United States population in 2000, but are expected to grow to be 19% of the U.S. population by 2030. As of July 2015, Florida's seniors already made up 19.4% of Florida's population. Florida's

senior population is known to have higher rates of chronic diseases than persons less than 65 years of age. This growing population with complex care needs is largely responsible for rising health care costs and presents an urgent need for innovative care delivery¹

- 28. Structure of the Program (TMC offers no comment).
- 29. Budget (TMC offers no comment).
- 30. Other factors, budget (TMC offers no comment)
- 31. Application process.

TMC may propose a pilot **Remote Patient Monitoring (RPM)** Project to replicate improvements in the care of chronically ill persons as reported in countless medical journals from Australian, European, an U.S. trials. The RPM system is expected to reduce the incidence of re-hospitalization, hospital length of stay (LOS), morbidity, and mortality by monitoring health indicators of patients afflicted with certain chronic diseases. The RPM system and procedures allows for more frequent assessment of patients' medical conditions from patients' residences by medical specialists at distant sites. It guarantees adherence and more frequent Continuity of Care (COC) hence lowering the cost and improving the conditions of the chronic diseases patients.

The TMC shall provide WGH credentialed physicians and patients with RPM 24/7 services. The RPM system measures and transmits test results of the PO2 (partial pressure of oxygen), glucose meter, lung volume (spirometer), 1 lead EKG (electrocardiogram), temperature, blood pressure, and weight. All system components are FCC and FDA certified. The system also complies with HIPAA and HIPAA HITEH regulations.

In the course of discharge planning, WGH Case Managers will select and propose patients to participate in the Project. If patients and their physicians' consent, upon discharge, TMC nurses will instruct patient and/or caregiver in the use of the non-invasive medical instruments that will be on loan and installed at patients' residences. It is understood that in consideration for the security and proper functioning of the equipment, participating patients must reside in a single family home or apartment, not an SNF, ILFs or ALFs. Patients' physicians set the normal parameters for measurements that, if deviates from norm, will trigger alerts and procedures prescribed by the physicians. Physicians may access results of patients' measurements at any time over secure VPN in compliance with HIPAA and HIPAA HITEH regulations.

Unlike other RPM services, TMC operate a monitoring centers staffed 24/7 by licensed nurses who receive data and interact with patients and their physicians.

Medicare/Medicaid has focused on chronic diseases where RPM is valuable in accomplishing much needed cost reductions. Consequently, we believe the pilot program should target the low-

 $^{^1}$ Florida's Economic Future & the Impact of Aging, The Florida Legislature Office of Economic and Demographic Research (March 17, 2014).

income over 65 years of age chronically ill patients covered by Medicaid. Hospital admission electronic health records (EHR) captures the information required to identify the target population and may be use to facilitate selection.

32. Criteria for selection of patients.

Hospitals' electronic health records (EHR) will facilitate the process of selecting prospective patients for the Project. In the course of discharge planning, EHR may be useful to culled by Diagnostic Related Group (DRG) codes for patients classified with chronic obstructive pulmonary disease (DRG 190-192), heart failure (DRG 291-293), and pneumonia (DRG 193-195). A mix of hospital-wide unplanned readmissions will also be selected. The hospitals' EHR system will produce a list of prospective patients and physicians from which to select those with the required characteristics willing to volunteer to participate in the Project. Final selection will be accomplished via review of patients' clinical history, the cooperation of hospital credentialed physicians, and consent of patients. To participate in the project, patients will be finally selected among low-income (HHS definition) Hispanic and Haitian local residents. Once selected, the connectivity will be provided by TracFone, our current broadband provider.

33. Prioritize project.

TMC believes that the three partners in the proposed project must focus on their respective business core functions. The broadband provider may be requested to provide "end-use equipment" such as hubs or other telecommunications equipment, but not medical devices containing proprietary data or Protected Health Information (PHI).

34. Eligible Healthcare Providers

TMC believes the pilot program should target low-income over 65 years of age chronically ill patients covered by Medicaid. Hospital admission electronic health records (HER) captures this information and may be use to facilitate selection.

35. Location.

Whether urban or rural, we must first consider the needs of the population. South Florida is home of a burgeoning needy elderly legal residents Hispanic population predominantly refugees from Cuba, Venezuela, Nicaragua, Colombia, and Puerto Rico. A hospital serving the target population described in previous paragraph should be prioritized for the proposed project.

36. Limiting pilot to hospitals with established telehealth?

If the emphasis is expanding the fiber optic infrastructure and promoting telehealth, the proposed project should prioritize hospitals that **have yet to implement** telehealth or RPM programs.

37. Facility-based eligible telecommunications carrier (ETC)

Should this RFI results in a **Request For Proposal (RFP)**, TeleHealthCare America intends to partner with the Westchester General Hospital, and TracFone to submit a proposal. On April 11, 2008, the Commission issued an Order designating TracFone as an ETC in its licensed service areas in the FCC-designated states pursuant to Section 214(e)(2) of the Act.

- 38. We concur on having the healthcare provider partner with an ETC.
- 39. We believe the proposed project should target the low-income over 65 years of age chronically ill patients covered by Medicaid irrespective of whether in an urban or rural setting.
- 40. Participating patients should be legal residents otherwise they would not be covered by Medicaid. Priority may be considered for participants who do not have broadband, but must not exclude the medically needy solely on this issue.
- 41. It is the function of a RPM service to be in periodic contact with participating patients. In the course of providing the service, the RPM will know if whether participant continues to use the broadband service. This information is available to the Commission by the telehealth/RPM service.
- 42. We concurs the program should support fixed and mobile broadband services. Redundancy may be useful to maintain connectivity.
- 43. In light that synchronous video and image transmissions are part of the provided telehealth service the Commission should consider 4G or 4G LTE bandwidth.
- 44. It is not possible to expect 100% reliability. Procedures of the RPM/Telehealth service must contemplate and address down-time in their policies and procedures.
- 45. Communications between hospital and emergency service already exists. EMS are already equipped medical equipment to monitor vital signs.
- 46. Established hospitals already have routers and servers.
- 47. RPM equipment should be provided by the RPM service. It will be part of the offer for the prescribed duration. The equipment is on no use without the monitoring service.
- 48. Unable to comment on this point. TeleMedCare America operates its own proprietary software to collect and transmit medical data. The software runs on its servers and medical devices it is not a mobile application.
- 49. The Westchester General Hospital serves about 5,000 patients per year. Assuming only 5% meets the eligibility criteria; we may serve about 250 eligible patients with RPM in one year and 750 over a three (3) year period for about \$206,250. As patients end treatment, they may

- be replaced for others. In other words, there may be 250 slots. Estimated is RPM service only. Improving broadband infrastructure and connectivity for participants must be calculated separately by TracFone. However, suggested funding seems adequate. To be consistent with Medicare/Medicaid metrics, for the purpose of reporting, data will be collected and reported from each participant 30 days following discharge from hospital.
- 50. We suggest a fixed-price contract with prospective price redetermination. *Adjustments based on actual costs of labor or material*. These price adjustments are based on increases or decreases in specified costs of labor or material that the contractor actually experiences during contract performance. The telehealth or RPM service to act as fiduciary agent, administer funds and payments to hospital and broadband provider.
- 51. We suggest a three year funding period with evaluations at quarterly intervals.
- 52. There should be no known regulatory barriers, except in the case of a project contemplating interstate interpretation of medical data. In such cases, the clinician in another state must be credentialed by the participating hospital. To be credentialed, the clinician must hold a state license. In every case, an initial face-to-face examination of patient by the attending physician must take place, but this routinely occurs at the hospital before the patient is discharged.
 - However, hospitals and medical professionals are prohibited by Medicare/Medicaid from offering anything of value that may be perceived as an inducement to receive medical services. To avoid a possible conflict and for the purpose of a project resulting from the expected RFP, the Commission may as the HHS-OIG to waiver grant recipients from provisions of the Anti-Kickback Statute or the Civil Monetary Penalties Law (42 CFR 1001.952, and 42 U.S.C. § 1320a-7a). This has been done for other pilot projects.
- 53. The Commission may ensure pilot program funding is appropriately spent prohibiting comingling of funds, requiring separate accounting and a fixed-price contract with prospective price redetermination.
- 54. The Commission may ensure that only eligible low-income patients receive program benefits by auditing the hospitals' EHR of patients. These records contain patient profiles and payment methods showing whether they are Medicaid recipient. The telehealth/RPM service should maintain copy of hospital information together with physicians' notes on each patient.
- 55. The three partner responding to any RFP resulting from this RFI must enter into an "associate agreement" with the hospital that covers Protected Health Information (PHI). In the case of TeleMedCare America has undergone HIPAA vulnerability assessments. Results disclose no conflicts of interest, security, or adverse environmental impact. Moreover, the entities are staffed by personnel that have undergone background screening and HIPAA training and system components are in full compliance with FCC, FDA, HIPAA and HIPAA HITECH for the protection of Protected Health Information (PHI).

- 56. Under Medicare standard "business associate agreement," Telehealth/RPM service, hospital, and broadband provider must comply with applicable HIPAA and HIPAA HITECH for the protection of Protected Health Information (PHI).
- 57. The TeleMedCare America partnership contemplates a possible proposal targeting low-income over 65 years-old chronically ill patients in urban areas. Lessons learned from the report from the Wireline Competition Bureau may not be pertinent to our aim.
- 58. In addition to metrics suggested in paragraph 32, notes on health of participants captured by the RPM service may serve to determine medical conditions, morbidity and mortality of participating patients. If required, a patient satisfaction survey may be administered at set intervals.
- 59. Metrics The success of the Project may be measured on improvements over the following conditions as reported in the "Medicare Fee-For-Service (FFS) Hospital Readmission 2017Q1 2017Q4, State of Florida: Westchester General Hospital.

Metrics	WGH 2017 Rates	1-year results	2-year results	3-year results
COPD 30-day Readmission Rate	25%			
Heart Failure (HF) 30-day Readmission Rate	50%			
Pneumonia (PNE) 30-day Readmission Rate	32%			
Acute Myocardial Infarction 30-day Readmission Rate.	25%			
Hospital-wide unplanned 30-day Readmission Rate [All cause]	33%			

Insofar as Medicare/Medicaid already publishes metrics for hospitals, we may avoid redundancy by adopting already compiled and validate data. Achievement over the above criteria correlates to substantial cost savings to Medicaid/Medicare.

- 60. The telehealth/RPM service collects and owns the medical data. Consequently, this entity should be responsible for reporting to the Commission. It may be less of a burden to the Commission to receive reports on a quarterly basis. Since we are primarily concerned with the health of participants and secondly with the expansion of the broadband infrastructure to serve a disadvantaged population, the project lead entity should be the telehealth/RPM service provider communicating with patients on a daily basis.
- 61. A patient satisfaction survey may complement metrics suggested in paragraph 59. However, it must be emphasized that Medicare already measure each hospital performance across meaningful conditions "Medicare Fee-For-Service (FFS) Hospital Readmission."

- 62. In the course of operations, TeleHealthCare America already interacts with patients and capture behavioral information. Other telehealth/RPM (synchronous or asynchronous) must also capture the information. It will take no effort to report this information at required intervals. For instance, TeleHealthCare America operates a monitoring center where the readings from medical devices at patients' homes first displayed in colors: green, yellow, or red. For details, the Nurses (RN) at the monitoring center depresses the colored icon and a dialog box appears with the actual readings and doctors' instructions to follow: e.g., a red icon may require calling emergency (911), while a yellow icon may instruct the nurse to remind the patient to take medication, and a green icon indicates stability. The interactions are encrypted and recorded in their servers and backed-up at cloud service.
- 63. In the case of a hospital, since Medicare/Medicaid already reports key metrics that serve as points of reference, all that may be required is to demonstrate improvements over past performance (see paragraph 59). To properly make assumptions relative to a control group requires drawing a statistical valid random samples (SVRS) from a finite population at a given confidence level and variability. Then the sample must be stratified to match the finite population. The process requires culling a large sample from the hospital EHR, it is time consuming, the hospital may object for security reasons, and it is totally impractical.
- 64. In the case of hospitals, cost savings over the preceding year may be calculate from data in the Cost Report hospitals must submit to Medicare at end of year.
- 65. The number of new subscriber/participants is a measure of enhancement to existing telehealth initiative. Once participant information is in a database, it is simple to link or sort files to detect any duplication relative to other government programs.
- 66. The ETC may employ a project management tool to illustrate measure program's effectiveness in deployment of the broadband over previously unchartered and underserved areas. Periodic updates of the tool could be made available to the Commission as part of the program.
- 67. Broadband adoption equates to the number of patients served. The Commission may contract separately for a socio-economic survey of patients' households. However, we must be mindful that the intended project is targeting low-income, chronically ill patients. The socio-economic advancement of the targeted group should not be the province of the project.
- 68. TeleHealthCare America and associates shall not be making a presentation.

END OF COMMENTS